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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/540,209	BRETON, GARY L.	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) 14-28 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This action is in response to Applicant's amendment and response received 5/30/2003 in response to the supplemental action mailed 3/14/2003. Claims 1-28 are now pending, claims 9-13 have been amended, while 14-28 are withdrawn from further consideration as being drawn to non-elected inventions. Claims 1-13 are currently under examination. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. All rejections not reiterated herein are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is Final.**

Specification

The specification is still objected to because of the following:

The title of the invention is still not descriptive. The elected claims are drawn to nucleic acids but the title is directed to nucleic acids and amino acids. A new title is required that is clearly indicative of the invention to which the elected claims are directed. Applicant asserted that the amended claim one rectified the objection but the even though an amino acid is being encoded, it is the polynucleotide encoding it that was elected for further prosecution in the claims, not the resulting amino acid or polypeptide ie. the polynucleotide, SEQ ID NO:4084 was elected not the amino acid, SEQ ID NO: 9306(See election response filed 9/5/2002.)

Response to Arguments

In response to Applicants arguments labeled as I and II from pages 4-11, these rejections have been withdrawn, as the present invention has an asserted utility of using the claimed compositions and methods involving *B. fragilis* as molecular targets for the identification of new

antimicrobial agents, probes for diagnostic assays, and targets for vaccine development as *B. fragilis* is a pathogenic organism.

With respect to the IDS filed, 6/25/2002, its contents have been considered in their entirety and references have been indicated as such on the PTO-892 form. The examiner had not received the references on the IDS when the First action on the merits of this case was written, even though applicant had submitted them.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A review of the language of the claims 9-10 indicates that they are drawn to a genus, i.e., any 20 or 40 nucleotides capable of hybridizing to a sequence set forth in SEQ ID NO:4084, a complement of SEQ ID NO: 4084, or an RNA of the same wherein U is substituted for T.

The search indicates that SEQ ID NO: 4084 is a novel and unobvious sequence. There is a single species explicitly disclosed(a molecule consisting of SEQ ID NO: 4084 that is within the scope of the claimed genus).

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claims encompass any sequence capable of hybridizing, splice variants and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because while SEQ ID NO: 4084 is a full open reading frame or ORF, when reviewing a claim that encompasses a widely varying genus such as any 20 or 40 nucleotides capable of hybridizing to a sequence set forth in SEQ ID NO:4084, a complement of SEQ ID NO: 4084, or an RNA of the same wherein U is substituted for T, the examiner must evaluate any necessary common attributes or features. In the case of a probe comprising at least twenty nucleotides of, or forty nucleotides that are hybridizable to a nucleic acid having an ORF sequence that is claimed with open language (comprising), the genus of, e.g., "a nucleic acid comprising a sequence capable of hybridizing," encompasses a variety of subgenera with widely varying attributes. For example, a probe comprising a nucleotide sequence consisting of at least twenty of SEQ ID NO:4084 or an isolated nucleic acid comprising a nucleotide sequence of at least forty nucleotides in length, wherein the sequence is hybridizable to a nucleic acid sequence of SEQ ID NO: 4084, is not representative of a genus as no information has been provided regarding the location or exact length of the 20 or 40 nucleic acid. Further, the probe or isolated nucleic acid could encompass any nucleic acid sequence minimally containing SEQ ID NO: 4084. While applicants have stated that the nucleic acids can be used as molecular targets for the identification of new antimicrobial agents, probes for diagnostic assays, and targets for vaccine development, the claims are not limited to nucleic acids having these functional properties.

A description of a genus of probes or isolated nucleotide sequences may be achieved by means of a recitation of a representative number of such, defined by a nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Here, the specification discloses only a single common structural feature shared by members of the claimed genus i.e., a sequence capable of hybridizing to SEQ ID NO:4084. Since the claimed genus encompasses genes yet to be discovered, splice variants, etc., the disclosed structural feature does not "constitute a substantial portion" of the claimed genus. Therefore, the disclosure of SEQ ID NO:4084 does not provide an adequate description of the claimed genus.

Weighing all factors, 1) partial structure of the DNAs that comprise SEQ ID NO:4084, 2) partial structure of DNAs that are capable of hybridizing to SEQ ID NO:4084, 3) the breadth of the claim as reading on genes yet to be discovered in addition to numerous splice variants and cDNAs, 4) the lack of correlation between the structure and the function of the genes and/or fusion constructs; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise a sequence capable of hybridizing under stringent conditions to SEQ ID NO:4084 and therefore the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No.4, pages 1099-1111, Friday January 5, 2001.

Response to Arguments:

In part **IV** of their response, applicants respectfully traverse this rejection under written description as they assert that disclosure of a single species can provide an adequate written description of a generic claim(Federal Register, Vol. 66, No.4), and further that a disclosure is sufficient if the disclosure teaches those skilled in the art what the invention is and how to

practice it(In *re Grimme, Keil and Schmitz*, 124 U.S.P.Q. 449, 502(C.C.P.A. 1960)). Applicants continue that the specification as filed provides ample support for the claims. Applicant further asserts that the functional domains for the dnaB protein in other species were well known in the art(Jezewska et al. for example) and because functional domains for the dnaB gene are well known in the art, one of ordinary skill in the art is able to identify and utilize a probe or an isolated nucleic acid of at least 20 nucleotides selected from the group consisting of SEQ ID NO: 4084. However, applicant should note that claims 9 and 10 read; "a probe comprising a nucleotide sequence consisting of at least twenty contiguous nucleotides" and "an isolated nucleic acid comprising a nucleotide sequence of at least forty nucleotides" respectively. The claims' "comprising" requirement allows the at least 20 and 40 language to include species that lack written description outside of the disclosed ORF of SEQ ID NO:4084. In addition, the specification as originally filed should provide support for the parts of the sequences being claimed that confer the functional properties to this invention. Although the specification included a table referencing the ORF of SEQ ID NO 4084 and the amino acid of SEQ ID NO: 9306 and their description as a *Rhodothermus marinus* dnaB gene and helicase respectively. The specification as originally filed provided no alignment with known dnaB genes or any sequence structure characteristic to such a gene encompassed in SEQ ID NO:4084. Furthermore, a sequence search by the examiner of SEQ ID NO: 4084 yielded very few sequence identities with known dnaB genes. The asserted utility of using the present invention as molecular targets for identification of new antimicrobial agents, probes for diagnostic assays, and targets for vaccine development should also be accompanied by a written description of the relevant parts, (ie the functionality-conferring structures) of the sequences of the present invention.

2. Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. The following factors have been considered in formulating this rejection (*In re Wands,* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Claims 11-13 are broadly drawn to any immunogenic composition comprising SEQ ID NO:4084, its complement, or an RNA of either and a pharmaceutically acceptable carrier, an adjuvant, or additional ingredients. The specification does not clearly set forth any of the "immunogenic compositions," "pharmaceutically acceptable carriers", "adjuvants", or "additional ingredients" and therefore the claims include all types of the aforementioned components. The specification does not at all enable an immunogenic composition comprising SEQ ID NO: 4048. The specification does not specify any examples of said immunogenic composition's ability to prevent or treat a *B. fragilis* infection. The specification further excludes any teachings of the biochemical effect of the vaccine with SEQ ID NO: 4084 and the way in which it confers the putative, resulting, preventative, or treated phenotype. The specification does not provide adequate guidance as to how to use the "pharmaceutically acceptable carrier", an "adjuvant", or "additional ingredients" with the immunogenic composition comprising a nucleic acid of SEQ ID NO: 4084 to treat or prevent *B. fragilis* infection. In the absence of

guidance in the specification and the general view of unpredictability that exists in the art of gene therapy, such random experimentation is considered to be undue. Moreover, the use of a composition comprising a gene or cDNA for treating a disease is highly unpredictable and the art of administering genes to cells in vivo to provide a new genetic activity or to perform gene therapy is not well developed. Therefore, the specification does not at all, enable how to use any immunogenic composition comprising SEQ ID NO:4084.

Response to Arguments:

In part **III,** applicants do not agree that claims 11-13 are not enabling for vaccines in the treatment or prevention of a *B. fragilis* infection. However, to expedite prosecution, applicant amended claims 11-13 to recite the term "immunogenic composition". Claims 11-13 still lack enablement for the use of "immunogenic compositions" in the treatment or prevention of a *B. fragilis* infection. In this amendment, the immunogenic composition retains the same weight attributed to the vaccine language as both denote a composition that will be used for the prevention and treatment of a *B. fragilis* infection.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Thursday from 7:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris
7/15/03

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER